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THE VIOLENT SIDE OF EMS

How to establish an effective prehospital restraint protocol p.39

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By John Erich, Associate Editor

The PROTOCOL PROCESS

Why do you do what you do, and how can you influence those decisions?

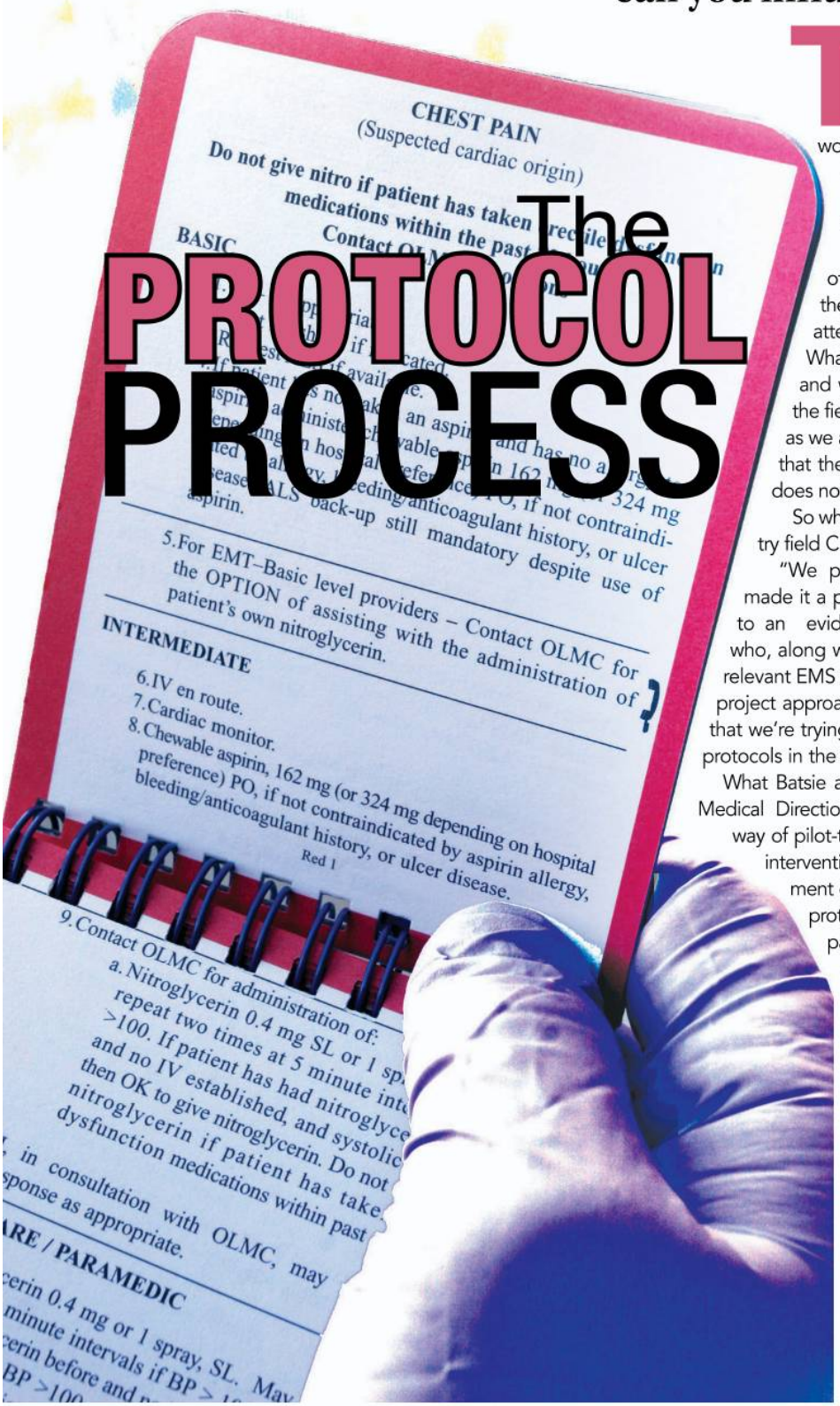

Photo by Dan Limmer

The prospect of delivering continuous positive airway pressure in the field excites a lot of people in EMS. It's fast, simple and works well against serious matters like congestive heart failure, chronic obstructive pulmonary disease and asthma. A number of jurisdictions already use it.

Problem was, three years ago, when a pair of providers in Maine wanted to introduce it in their state, there wasn't a huge body of evidence attesting to its efficacy outside hospital walls. What data there was came largely from hospitals, and while those findings might have translated to the field, they also might not have. Prehospital care, as we all know, often poses challenges and variables that the safe, controlled environment of the hospital does not.

So what was a progressive EMS type who wanted to try field CPAP to do?

"We probably could have just gone ahead and made it a protocol, but we really are trying to transition to an evidence-based approach," recalls Dan Batsie, who, along with a colleague, first broached the notion to relevant EMS authorities in Maine. "So we designed a pilot project approach, and what's evolved out of it is a process that we're trying to model into a method for delivering new protocols in the state."

What Batsie and Co. did, with support from Maine's EMS Medical Directions and Practice Board, was initiate a new way of pilot-testing new or not-as-proven-as-we-might-like interventions. It allows sytems to voluntarily implement emerging capabilities like CPAP—under a test protocol and close scrutiny designed to protect patients—while generating important data that could aid other systems wrestling with the decision down the line. It's not the only way to develop a new protocol, but it's one with significant benefits.

"A pilot project basically allows us to handle it in small portions," says Batsie, education coordinator for the Northeastern Maine EMS Council, the governing body for a four-county region in the northeastern part of the state. "If services want to have CPAP, great. If they don't, they don't have to spend any money or do anything. But it enables services to prepare: They can join the pilot project and begin operating under the requirements and parameters that will likely come with a new CPAP protocol if and when it's implemented statewide."

The Benefits of Statewide Protocols

Five benefits to having statewide EMS protocols, according to Pennsylvania medical director Doug Kupas, MD, whose commonwealth recently implemented them:

1. Uniformity: "The Institute of Medicine report called for more uniform treatment of injuries and illnesses across the country, so all patients receive the current standard of care at the most appropriate location," Kupas notes. As well, "EMS has people who work several jobs, and it doesn't make sense for them to have to remember one dose of Lasix when they work on Monday afternoons and another on Tuesday evenings, when they're at another job across a regional line."

2. Evidence base: "The things we do have good evidence for, I think we need to incorporate," Kupas says. "By having statewide protocols, it allows us to do that with a standard expectation."

3. Current standards of care: Pennsylvania's new statewide protocols reflect the most recent AHA CPR/ECC guidelines. "Doing that across the 16 regions," Kupas says, "would have been a huge effort. Some regions have a limited number of active medical directors and advisors and even supervisory EMS personnel, so for every one to incorporate new things and keep them up to date can be more difficult than doing it statewide."

4. Standardization beyond protocols. Going statewide also allows standardization of things like educational curricula, continuing education courses, ambulance equipment and drug lists, scopes of practice and complaint investigations.

5. Disaster preparedness. Pennsylvania contributed personnel and assets to the Katrina response, but they came from different regions and operated differently. "Here was a group going out of state, all functioning under different protocols," says Kupas. The same thing happened intrastate when strike teams from multiple regions responded to major flooding.

SOMETIMES SIMPLE, SOMETIMES NOT

A story on EMS protocol development comes with the standard caveats: 50 states, countless cities and counties and regions, different rules and procedures and environments, and so on. Processes described here may not resemble yours. But it is illuminating to talk about how EMS systems typically integrate new developments and technologies in the fast-changing world of prehospital emergency medicine.

Sometimes it's simple: When the evidence for something is clear, abundant and convincing, you just do it. Maybe a medical director can write and impose a new protocol unilaterally, maybe a board has to vote, but if pertinent questions about safety and effectiveness are satisfactorily answered, it can and should be done promptly.

"You want to change or add protocols for good reason—usually something scientific," says Jim Augustine, MD, medical director for the Atlanta Fire Department. "Say something is published that shows a piece of equipment is dangerous, or if something is

Protocols and Similar Things

A quick note of definition: The term *protocols* refers to expected specific medical care: If *x*, then do *y*. They are sometimes more precisely referred to as *medical protocols*. Related terms like *SOPs*, *SOGs/guidelines*, *standing orders* and *operational protocols* typically govern a department's tactical or operational practices.

suddenly not available—if bretylium, for example, became unavailable, and you needed a second-line drug after lidocaine. You'd work quickly to institute that kind of change, and then make the necessary supply or equipment changes."

What's frequently the case in EMS, however, is that the evidence isn't clear, abundant and convincing. Maybe something, as with CPAP, is great in hospitals but relatively unproven in the field. Maybe a new device, like the AutoPulse, demonstrates promise in some studies but gives pause for concern in others. Maybe your circumstances differ from those of published trials, so you can't generalize their conclusions. Then the process gets a bit trickier. System bosses will have to weigh the evidence and decide if the potential benefit is worth any potential risk. They will take into account any existing literature, as well as position papers and other information from physician groups like ACEP or NAEMSP. Input is often solicited from field providers, often through formal representation on some kind of decision-making committee. And they'll likely want to know what their peers in other systems and states are doing.

"It's usually a matter of discussion, and then people looking at the various parts of implementing something that doesn't exactly have the full science to justify it," says Augustine. "You get feedback from the people in the field, and you can have different committees or groups look at pieces of the protocol. Then you put together, in a rational process, any changes that are needed."

CASE STUDY: PENNSYLVANIA

For a case study of the development process, consider Pennsylvania, which moved to statewide BLS protocols in 2004 and statewide ALS protocols late last year. Protocols were previously developed independently within each of the state's 16 regions.

"We started by bringing about 80 people together for a meeting," explains Doug Kupas, MD, medical director for the Pennsylvania Department of Health's Bureau of EMS. "About half were physicians, and half were EMS personnel. It included representation from across the commonwealth and from other organizations of interest, like our state chapter of ACEP and the state trauma system. We basically divided up the work projects into groups, and a committee developed a standard template to use. Then we gathered the groups' input on protocols within

Other Things to Keep in Mind

Some other aspects to consider when changing or adding protocols, according to Atlanta Fire Department medical director Jim Augustine, MD:

- **Training and testing:** "These are important elements people can forget about," Augustine says. "Once you've developed a protocol, everybody has to be trained on it."
- **Keep it simple:** "Medics feel most comfortable with a finite set of things to do and ways to approach patients, not an infinite number. The majority don't want to carry a 50-pound drug box into every house."
- **Transport distances:** "There are really significant differences to whether you're working for an agency that's relatively close to hospitals or far away. If you're far away or do a lot of interhospital transfers, you'll have to broaden your protocols and look at doing more second- and third-line things. Agencies that operate close to hospitals can keep things simpler."
- **Safety *uber alles*:** "Everything should be looked at from a safety perspective, and how quality improvement can benefit patient care."

their given areas and put that out as a rough first draft. We had an open comment period and then four or five additional drafts. Each was more honed down, and followed with its own comment period and another meeting. The final meeting was for the 16 regional medical directors, and we had unanimous support from those who were present."

That process of subsequent levels of refinement left the state's medical directors generally pleased with the end product. And where it didn't yield consensus, it yielded flexibility.

"When there was good evidence for a particular way of doing something, we tried to make things as evidence-based as possible," says Kupas. "But when there were strong opinions on conflicting sides of things that were both reasonable, we allowed options. We don't mandate, for example, the use of diazepam or midazolam or lorazepam; service medical directors can use any of the three, but they have to carry one of them. So the protocols accommodate some flexibility at both the service level and the regional level, but they still define the basic expected care statewide."

This flexibility includes allowing regions to implement addition protocols, on top of the state minimums, if they have a particular reason or need.

"For example," says Kupas, "we can't, at this point, do a statewide protocol for something like destinations for ST-elevation MIs, because we don't have any kind of statewide system for designating the receiving centers. But a region that perceives a need could do a regional protocol for something like that. So there's still the opportunity for additional regional protocols on top of the statewide protocols."

CASE STUDY: CONNECTICUT

Connecticut provides another example of reconciling differing protocols in a quest for standardization. The state has five EMS regions, within which medical control is provided by sponsor hospitals. That means protocols can vary from hospital to hospital and service to service, even within regions.

In the state's North Central Region, leaders began pushing a few years back to standardize protocols among their hospitals. Things were rather confusing.

"In my service, half our medics were sponsored by Hartford Hospital, and the other half by Saint Francis," recalls Peter Canning, EMT-P, now the paramedic representative to the region's medical advisory committee. "The Saint Francis medics carried Valium for seizures, the Hartford medics carried Ativan. The Saint Francis medics could use Cardizem, the Hartford medics could not. And medics at other hospitals had their own protocols."

Further complicating things, many

The Secrets of My Success

Secrets to success in passing new protocols, according to Connecticut medic Peter Canning, who serves on the advisory committee that standardized protocols within his region:

1. Do the research to show the evidence behind what you're proposing: Change has to be for good reason.

2. Do the research to show that other services are using similar protocols: "No physician wants to be the first to adopt a new protocol," Canning says.

3. Be patient and willing to compromise: "Our regional protocols would fall apart if any hospital felt protocols were being forced on them by others. We try to pass everything by consensus."

4. Do the paperwork: "If you want to have a policy or protocol on something, write it out just like it will appear. People will quibble and make changes, but as long as you keep coming back with a document, eventually it will get done."

providers worked multiple jobs with different services, meaning they had to remember different protocols at different times. That's a recipe for problems.

Current state section chief Gary Wiemokly, then clinical coordinator at St. Francis, spearheaded the push for standard regional protocols. A series of meetings ultimately got all eight North Central hospitals onto the same page, and the region now has standard protocols.

At least one other region in Connecticut does too, and all are working toward them. Variation still exists, however, from region to region. The next goal, then, is to work to minimize those differences. That may ultimately mean statewide protocols, but for now it merely entails the simple sharing of ideas and approaches.

"The chair of our regional medical advisory committee is also chair of the state MAC, and it's his desire that we move toward uniformity in the regions," says Canning. "In practice, that's meant sharing our protocols with other regions. On larger issues we try to work with the other regions to develop and agree upon a state policy."

CASE STUDY: LOUISVILLE

The protocol development process often represents an opportunity for street-level providers to help shape the kinds of systems they work in. They're the front lines of deployment for any new intervention, and their experience and insights are valuable for the higher-ups setting policy. Many systems have mechanisms by which field personnel can suggest and weigh in on changes. The new EMS service in Louisville is one that's embraced that concept.

Louisville Metro EMS debuted in early 2005, after EMS was split from

Expert Opinions

- **NAEMSP:** The National Association of EMS Physicians offers a range of position papers at www.naemsp.org/position.html.
- **ACEP:** Under the "Practice Resources" section of its website (www.acep.org), the American College of Emergency Physicians provides a variety of clinical and nonclinical policy statements.
- **Porter's:** Jones & Bartlett now offers *Porter's EMS Protocols*, a ready-made set developed by William Porter, clinical manager for Air Life of Oregon. They are used by more than 400 U.S. services, as well as the Coast Guard. See www.emsprotocols.com.

the city's fire department and merged with the county third service. Both sides had their own protocols, which were initially integrated into a single set as things got running.

But now that LMEMS has its sea legs, so to speak, it has further created a Medical Steering Committee to help funnel provider input into protocol development and change.

"We got a volunteer team of paramedics, EMTs, supervisors and firefighters together, and they put out a survey to the entire field," explains Neal Richmond, MD, the service's medical director and CEO. "They said 'It's time to look at all our protocols anew. What would you, the field, like to do in terms of new protocols, skills and devices? What, in the old protocols, would you like to see revised, and what do you think we shouldn't be doing anymore?' What we got was a long list—everything from doing field clearance for spinal immobilization to EMTs taking on Combitubes to medics taking on new drugs or using the EZ-IO."

The committee prioritized the suggestions and pared the list down to the items deserving first attention. They were then charged with reviewing the scientific literature and coming up with a rationale for change. Changes must have a scientific basis—Richmond and his boss, the mayor, want a system that's data-driven and evidence-based.

Finally, armed with good evidence and compelling arguments, members were charged with developing draft protocols, accompanied by outlines of training and quality-assurance packages.

"The idea is, I want to step back and let the field really develop the critical evaluation skills to do this themselves," Richmond says. "We'll provide the guidance about how to do it, but it's really up to them as to where they want to move the service and what they consider important."

The benefits here look to be numerous: Medics can shape a system that, within the bounds of good evidence, is as aggressive or conservative as they'd like it to be. They'll understand the scientific basis for what they do, the process of incorporating science into practice, how to train providers on it and how to safeguard patients with robust QA (personnel will even rotate as training and QA officers). LMEMS providers will, to large degree, "own" their system.

THE PRACTICAL AND POLITICAL

Beyond the evidence, there are other considerations when weighing new or changed protocols. Practical and political matters, however unpleasant, will always impact the discussion.

"Political considerations include price, the ability to train and test, and how you work with your partners within your region," says Augustine. "Say you're looking at using amiodarone for dysrhythmia monitoring. There's a bit of literature supporting it, and a bit that says it's not useful or appropriate. So negotiations may consider not only the science behind it, but how easy it is to store and administer and train people on. What's the supply? How much does it cost? How often will you use it? Those are the kinds of factors that come into play when the science isn't so exact."

Also, "Any committee will have internal politics," says Canning. "The No. 1 obstacle I've found is resistance to change. The way to overcome this is to thoroughly prepare

your arguments, show the research, show how it's working in other places and explain how the change will help. It also helps to enlist supporters in advance and develop personal relationships."

The QA component is also vitally important when protocols are added or altered. Whatever the literature says, systems must know that their new or improved interventions are actually helping patients, not hurting them.

At the micro level, services recognize this. And it's one of the factors that, at the macro level, drives what seems to be a current trend toward standardization of protocols across regions and states. If everyone's doing the same thing the same way, it's easier to compare apples to apples and draw valid conclusions about how things work.

"Our protocols were written with performance parameters, which are basically QI parameters," says Kupas, who also chairs the National Association of EMS Physicians' Standards and Clinical Practice Committee. "They recommend potential benchmarks, and we'll be able to use those to send out service-specific or region-specific quality evaluations. Those won't all center around the protocols, but it will be beneficial to have a standard that's set.

"In addition, there's a national effort right now, led by NHTSA, to look at quality indicators, and a number of the things that are on their list, we have in our parameters already. That'll help drive things too."

The Maine CPAP project initially included five communities, and Portland's Maine Medical Center picked it up as a research project as well. Participants summarized their findings to the Medical Directions and Practice Board every six months until the project's original end date, May 2005. But at that point, board members told them to keep going. The project now includes 11 towns, with more being added and more data being accumulated.

"I think we've proven now that CPAP in Maine is not harmful, and that it probably is helpful, although our evidence hasn't been overwhelming," says Batsie. "So it's likely going to become a [statewide] protocol. We've gone from five services contributing data to 11 really filling the database up. At least under our circumstances, CPAP isn't something we're going to use every week, but 11 is certainly better than five."

INFORMED INVOLVEMENT

The not-so-subtly couched lesson here is that, as Batsie says, "Protocols get changed by people

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who show up." Most systems will provide some kind of opportunity for providers to influence the process and help shape their own destinies. It would be nice if they cared enough to do so.

"Every year we put out a notice that if you have any protocol ideas, please forward them. Very rarely do we get stuff," says Canning. "When I joined our medical advisory committee, I wanted to reach out and get more field involvement—most of the paramedics didn't even know we existed. But one of the things with the field people is that you work so much, a lot of times, you don't really know what else is going on. So we can sit here and pass all the protocols and make all the changes we want, but we have to find some way to get it all out to the people on the street."

Response in Louisville has been somewhat better. There, providers have responded enthusiastically to the chance to put their stamp on things.

"I've gotten a whole slew of e-mails," says Richmond. "Everybody thinks the steering committee is a great thing. People seem to feel 'If we don't take ownership of this, we'll never be the best-practices model we're supposed to be.' And that's really gratifying."

The argument here, at its core, isn't really about simple involvement, though. It's about *informed* involvement. It's about taking a position you can back up with more than anecdote and spleen. Providers who know *why* they do what they do are likely to be better providers.

"The trouble we often have in EMS," Batsie says, "is that there are people who want to come to the table and pound their fists and say 'We need this.' But there are very few who are willing to step up and say 'We need this, and this is why. Here's how I can *prove* we need this.' And if we really want to play at the big boys' table in healthcare, that's what we have to do." ■

We Want To Hear From You!

Can you participate in the protocol change and development process at your agency? Do you, or would you if you could? We're asking a few simple questions about the issue at www.emsresponder.com. Stop by and share your thoughts, and help us get a fuller picture of how providers help shape the protocol process across the U.S.